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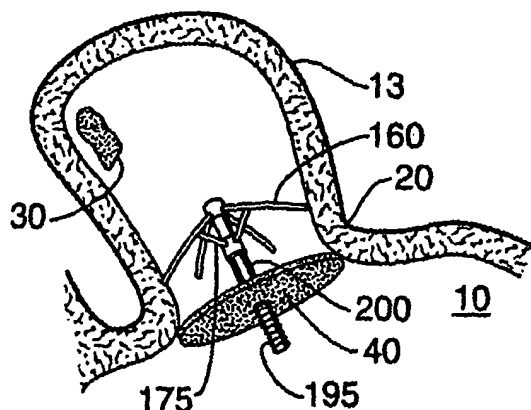
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(54) Title: BARRIER DEVICE FOR OSTIUM OF LEFT ATRIAL APPENDAGE



(57) Abstract: A membrane applied to the ostium of an atrial appendage for blocking blood from entering the atrial appendage which can form blood clots therein is disclosed. The membrane also prevents blood clots in the atrial appendage from escaping therefrom and entering the blood stream which can result in a blocked blood vessel, leading to strokes and heart attacks. The membranes are percutaneously installed in patients experiencing atrial fibrillations and other heart conditions where thrombosis may form in the atrial appendages. A variety of means for securing the membranes in place are disclosed. The membranes may be held in place over the ostium of the atrial appendage or fill the inside of the atrial appendage. The means for holding the membranes in place over the ostium of the atrial appendages include prongs, stents, anchors with tethers or springs, disks with tethers or springs, umbrellas, spiral springs filling the atrial appendages, and adhesives. After the membrane is in place a filler substance may be added inside the atrial appendage to reduce the volume,

help seal the membrane against the ostium or clot the blood in the atrial appendage. The membranes may have anticoagulants to help prevent thrombosis. The membranes may be porous such that endothelial cells cover the membrane presenting a living membrane wall to prevent thrombosis. The membranes may have means to center the membranes over the ostium. Sensors may be attached to the membrane to provide information about the patient.

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BARRIER DEVICE FOR OSTIUM OF LEFT ATRIAL APPENDAGEField of the Invention

The invention relates to a membrane or plug structure applied to the ostium of an atrial appendage
5 for preventing blood flow and physical connection between an atrium of the heart and the associated atrial appendage or appendages to isolate an atrial appendage and prevent thrombus leaving therefrom.

Description of the Related Art

10 There are a number of heart diseases (e.g. coronary artery disease, mitral valve disease) that have various adverse effects on the heart. An adverse effect of certain cardiac diseases, such as mitral valve disease, is atrial (or auricular) fibrillation.
15 Atrial fibrillation may result in pooling of blood in the left atrial appendage. Blood pooling may also be spontaneous. When blood pools in the atrial appendage, blood clots can form and accumulate therein, build upon themselves, and propagate out from the atrial appendage
20 into the atrium. These blood clots can then enter the systemic or pulmonary circulations and cause serious problems if they migrate from the atrial appendage and become free in the blood stream and embolize distally

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into the arterial system. Similar problems also occur when a blood clot extending from an atrial appendage into an atrium breaks off and enters the blood supply. Since blood from the left atrium and ventricle supply the heart and brain, blood clots from the atrial appendages can obstruct blood flow therein causing heart attacks, strokes or other organ ischemia. It is therefore necessary to find a means of preventing blood clots from forming in the atrial appendages and to prevent these blood clots, once formed, from leaving the atrial appendages to the heart, lungs, brain or other circulations of the patient which can cause heart attacks or strokes or other organ ischemia.

Patent 5,865,791 relates to the reduction of regions of blood stasis and ultimately thrombus formation in such regions, particularly in the atrial appendages of patients with atrial fibrillation. More specifically, the invention relates to procedures and devices for affixing the atrial appendages in an orientation that prevents subsequent formation of thrombus. The invention removes the appendage from the atrium by pulling on it and putting a loop around it to form a sack of the atrial appendage and then cut off from the rest of the heart.

Patent 5,306,234 relates to a method for surgically closing the passage between the atrium and the atrial appendage or severing the atrial appendage.

Other methods of treatment include surgically removing the atrial appendages to prevent blood stasis in the atrial appendages.

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Summary of the Invention

The invention provides a membrane or plug structure for preventing blood from entering the atrial appendages to form blood clots and prevents blood clots
5 formed in the atrial appendages from exiting therefrom which may cause heart attacks, strokes and other embolic events. The membrane covers the ostium of the atrial appendage and effectively isolates it from the atrium. It may be larger than the ostium of the
10 appendage, and extend over an area larger than the appendage ostium. It is percutaneously delivered to the ostium of the atrial appendage by a catheter and then expanded to cover the ostium and has a means to attach the membrane over the ostium. The membrane
15 itself is may be porous or non-porous. In the case of a porous membrane, it can become infiltrated with cells so that it becomes a "living" structure, and can develop an endothelial/endocardial lining to enable it in turn to become a non-thrombogenic surface. There
20 are many means for fixing the membrane to cover the ostium of the atrial membrane. The membrane's attachment devices have a means for self-centering the membrane over the appendage ostium. The membrane may be glued on, or have a stents or prongs which pass
25 through the ostium and extend into or through the atrial appendage. Alternatively an anchor in the wall of the atrial appendage may be tethered to the membrane for holding the membrane in place. Springs may also extend between the anchor and the membrane to hold the
30 membrane against the ostium. The membrane may also be connected to a tether, elastic tether or spring and placed through the atrial appendage wall for holding the membrane against the ostium and may pull on the

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atrial appendage such that its volume is reduced or eliminated, trapping and isolating blood clots therein. Thrombin, activated fibrinogen, or other biologic filler may be placed in the appendage after it has been
5 sealed, with the express purpose of clotting the blood in the appendage, yet preventing clot from escaping the appendage.

Part of the device may involve a suction apparatus to remove clots that are already in place.
10 The membrane placement may require closure of an atrial septal defect created by the placement of this appendage occluder device.

Alternatively the membrane may be held in place by a coiled spring filling the volume of the
15 atrial appendage. The membrane may also fill the atrial appendage itself preventing blood from entering or blood clots from leaving.

The membrane itself may be porous or non-porous. In the case of a porous membrane, it can
20 become infiltrated with cells so that it becomes a "living" structure, and can develop an endothelial/endocardial lining to enable it in turn to become a nonthrombogenic surface. It thus can develop an endothelium and with time becomes highly
25 biocompatible. It may be heparin coated to prevent thrombus from forming on the membrane surface, immediately after placement and until it infiltrates with cells and/or develops an endothelial covering.

The device, when implanted in the atrial
30 appendage, may also have the ability to perform electrical monitoring of the heart. This would consist of two or more electrical contacts placed apart on the device, and connected to signal conditioning circuitry

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for determination of cardiac features such as rhythm of the atria or ventricles. Another sensor on the device could measure pressure of the atria, atrial appendage, or ventricular end diastolic pressures (left or right) through the open mitral or tricuspid valves. A suitable telemetry system would be used to telemeter this important electrical and hemodynamic information non-invasively outside the patient. Also, memory could be present on the device in order to record the information for later recovery via noninvasive telemetry.

This device can also be used to close fistulae or connections elsewhere in the body, such as in the colon or bronchopulmonary systems. Another application of the device would be to seal and strengthen false aneurysm of the left ventricle by holding the membrane against the false aneurysm. The same principles apply, whereby the membrane is held against the fistulae or false aneurysm, held in place by the spring or prong mechanisms.

The device can also be used to chemically ablate the myocardial tissue of the atrial appendage in order to help limit or eliminate the electrical propagation of atrial fibrillation.

25 Objects of the Invention

It is an object of the invention to reduce the volume of an atrial appendage to reduce the size of the region for potential blood stasis formation, and consequently the effective volume of the affected atrium.

It is an object of the invention to measure hemodynamics pressure (or flow), or electrical signals

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in the heart and telemeter them outside the body for diagnosis or monitoring.

It is an object of the invention to be able to close fistulae or connections elsewhere in the body, such as in the colon or bronchopulmonary systems.

It is another object of the invention for the membrane to be placed in a false aneurysm to strengthen this defect, and to avoid surgery.

It is an object of the invention to reduce the region of static blood in the atrial appendages and hence the thrombogenicity of the atrium.

It is an object of the invention to prevent blood clots from forming in the atrial appendages.

It is an object of the invention to replace the ostium of the atrial appendage with a non-thrombogenic, biocompatible surface that prevents blood clots from forming.

It is an object of the invention to provide a porous membrane surface which becomes lined with endothelial or endocardial cells.

It is an object of the invention to isolate the atrial appendage from the atrium proper and prevent communication through which thrombus could migrate.

It is an object of the invention to minimally invasively prevent blood clots from forming in the atrial appendages and escaping therefrom.

It is an object of the invention to provide a filter between the atrium and atrial appendage to prevent blood clots from flowing therebetween.

It is an object of the invention to fill the atrial appendage with a material to prevent blood clots from leaving the atrial appendage.

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It is an object of the invention to remove thrombi from the atrium via suction or other means.

It is an object of the invention to provide a means for securing a membrane over the ostium of the atrial appendage that is colonized with cells and provide a highly biocompatible surface including but not limited to endothelialization.

It is an object of the invention to prevent thrombus by use of heparin or other antithrombogenic substance on or eluted from the membrane.

It is an object of the invention to seal the membrane with a substance injected into the atrial appendage.

It is an object of the invention to clot the blood inside of the atrial appendage after the membrane is in place with a substance injected into the atrial appendage.

It is an object of the invention to inject a substance into the sealed appendage to ablate the myocardial cells of the appendage, in order to limit the propagation of atrial fibrillation.

It is an object of the invention to ensure the membrane is centered over the ostium of the atrial appendage.

It is an object of the invention to accurately place the membrane over the ostium of the atrial appendage.

Other objects, advantages and novel features of the present invention will become apparent from the following detailed description of the invention when considered in conjunction with the accompanying drawings.

Brief Description of the Drawings

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FIG. 1 is a partial cross sectional view of a heart showing a catheter entering the left atrial appendage using a retrograde procedure from the aorta.

FIG. 2 is a partial cross sectional view of a heart showing a catheter entering the left atrial appendage using a transeptal procedure from the femoral vein or superior vena cava.

FIG. 3 is a partial cross sectional view of a heart showing a catheter entering the right atrial appendage from the jugular vein or optionally from the femoral vein.

FIG. 4 is a partial cross sectional view of a portion of a heart showing an atrium and its associated atrial appendage.

FIG. 5 is a partial cross sectional view of a portion of a heart showing an atrium and its associated atrial appendage with a porous membrane having flexible wire prongs with atraumatic bulbs to hold the membrane in place and electronics built into the membrane.

FIG. 6 is similar to FIG. 5 with the atraumatic bulbs removed so that the flexible wire prongs may puncture the atrium wall and secure the membrane to the atrial appendage and a centering rim added to the membrane.

FIG. 7 is a partial cross sectional view of a portion of a heart as in FIG. 5 with a stent portion between the membrane and the prongs.

FIG. 8 is the same as FIG. 7 with the atraumatic bulbs removed so that the flexible wire prongs may puncture the atrium wall and secure the membrane to the atrial appendage.

FIG. 9 is a partial cross sectional view of a portion of a heart showing an atrium and its associated

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atrial appendage with a porous membrane having a large expandable stent to hold the membrane in place.

FIG. 10 is a partial cross sectional view of a portion of a heart showing an atrium and its associated atrial appendage having an anchor and a
5 tether to hold the membrane in place.

FIG. 11 is a partial cross sectional view of a portion of a heart showing an atrium and its associated atrial appendage having an anchor and a
10 spring to hold the membrane in place, a centering rim on the membrane and a centering cable.

FIG. 12 is the same as FIG. 11 with the spring filling the atrium to help hold the membrane in place.

15 FIG. 13 is a partial cross sectional view of a portion of a heart showing an atrium and its associated atrial appendage with the membrane adhesively being held in place.

FIG. 14 is a partial cross sectional view of a delivery catheter having a disk, a spring and
20 membrane therein.

FIG. 15 is a schematic view of a disk, spring and membrane after being expanded out of the delivery catheter of FIG 11.

25 FIG. 16 is a partial cross sectional view of a portion of a heart showing an atrium and its associated atrial appendage having a disk, a membrane and a spring therebetween.

FIG. 17 is a partial cross sectional view of a portion of a heart showing an atrium and its associated atrial appendage shown in a collapsed
30 position.

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FIG. 18 is a partial cross sectional view of a portion of a heart showing an atrium and its associated atrial appendage having a disk, a spring, a membrane and vacuum in the catheter.

5 FIG. 19 is a partial cross sectional view of a portion of a heart showing an atrium and its associated atrial appendage having a membrane material fill the atrial appendage.

10 FIG. 20 is a partial cross sectional view of a portion of a heart showing an atrium and its associated atrial appendage showing an umbrella folded for entering the atrial appendage.

15 FIG. 21 is a partial cross sectional view of a portion of a heart showing an atrium and its associated atrial appendage showing the umbrella opened in the atrial appendage to secure the umbrella into the wall of the atrial appendage.

20 FIG. 22 is a partial cross sectional view of a portion of a heart showing an atrium and its associated atrial appendage showing the umbrella and membrane sealing the ostium of the atrial appendage.

25 FIG. 23 is a partial cross sectional view of a portion of a heart showing an atrium and its associated atrial appendage showing a stent having a membrane for blocking the ostium of the atrial appendage.

30 FIG. 24 is a partial cross sectional view of a portion of a heart showing an atrium and its associated atrial appendage showing the atrial appendage reduced to a minimum volume by a disk and spring squeezing the appendage against a membrane.

Description of the Preferred Embodiments

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Although atrial fibrillation results in pooling of blood in the left atrial appendage and the majority of use of the invention is anticipated to be for the left atrial appendage the invention may also be
5 used on the right atrial appendage and in general for any aperture in the body which needs to be blocked to prevent blood from flowing therethrough or therefrom.

As shown in FIG. 4 a thrombus 30 may occur from pooling of blood in the left atrial appendage 13
10 due to poor circulation of blood therein when the patient experiences atrial fibrillation. To prevent thrombus 30 from forming in the left atrial appendage 13 or to prevent thrombosis formed therein from leaving and entering the blood stream which may cause a heart
15 attack, a stroke or ischemia, a membrane 40 is placed across the ostium 20 of the atrial appendage 13. The membrane 40 can be made of Teflon®, felt, Dacron®, silicone urethane, Gortex®, metal fibers or biocompatible polymers.

20 The membrane 40 may be a porous membrane. Porous membranes may consist of a biocompatible polymer which is porous, having pore sizes ranging from 20-100 microns. The pores may also be larger or smaller in rare cases. The membrane may also be a porous metal or
25 a metal mesh of fine fibers which permit ingrowth of cells and covering with endothelial cells. The membrane may be coated with anticoagulant, or elute the anticoagulant.

The porous membrane colonizes with cells from
30 the heart and so walls off the ostium 20 so that blood can not flow into the left atrial appendage 13 to form thrombus 30 and more importantly no thrombus 30 formed

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can leave the left atrial appendage 13 to cause heart attacks, strokes or ischemia.

The membrane 40 placed over the ostium 20 should be antithrombotic. In order to make the
5 membrane antithrombotic heparin or other anticoagulants or antiplatelet agent may be used on the membrane 40.

When porous membranes 40 are used which have an ingrowth of cells covering the membrane with endothelial cells the endothelial cells present a
10 smooth cellular wall covering the membrane which prevents thrombosis from occurring at the membrane.

When blood pools in the left atrial appendage 13, thrombus 30 (blood clot) can accumulate therein, build upon themselves, and propagate out from
15 the left atrial appendage 13 into the left atrium 11 entering the blood stream, leaving the heart and can block blood flow to the heart, brain, other organs, or peripheral vessels if it becomes lodged in the arteries thereof.

20 FIGS. 1 and 2 show a cross section of a human heart showing a thrombus 30 in the left atrial appendage 13. The figures also show the atrial appendage ostium 20 which is to have a membrane 40 placed over it to prevent the thrombus 30 from escaping
25 out of the atrial appendage 13 into the left atrium 11 and thus into the blood stream, which could cause a stroke, a heart attack or ischemia. The membrane 40 also prevents blood from entering the left atrial appendage 13 where it could pool due to poor
30 circulation and become a thrombus.

FIG. 3 shows a cross section of a human heart showing a thrombus 30 in the right atrial appendage 23.

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The right atrial appendage 23 can be treated in the same manner as the left atrial appendage 13.

FIG. 4 shows a cross section of the left atrium 11, the ostium 20 and the left atrial appendage 13 having a thrombus 30 therein.

FIG. 5 shows a first embodiment of the invention wherein the porous membrane 40 has a plurality of flexible prongs 50 which may be made from a shape memory alloy, such as Nitinol®, for retaining a predisposed shape. The prongs 50 may be atraumatic so that they do not perforate the left atrial appendage 13. The prongs 50 may have atraumatic bulbs 55 on their tips so that the tips of the prongs 50 will not perforate the left atrial appendage 13. Nitinol® has the property of being able to be placed in a catheter in a compact configuration and then expanded when released from the catheter to a predetermined memory shape. The shape selected may be for the prongs 50 to curve around the lip of the ostium 20 and then hug the sides of the left atrial appendage 13. In this manner the membrane 40 will securely block the ostium 20 preventing blood from entering and particularly for preventing thrombosis 30 from leaving the left atrial appendage 13.

The membrane 40 is self centering over the ostium 20 of the left atrial appendage 13, by placing the prongs 50 in a circle around the membrane 40 such that the prongs 50 fit against the wall of the left atrial appendage 13 of or within the lumen of the ostium 20 to center the membrane 40 over the ostium 20. The membrane 40 may also be centered by a centering rim 65 (see FIG. 6) attached to the back (appendage) side of the membrane 40 that protrudes into the ostium 20

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for centering. The centering rim 65 has a diameter of less than the diameter of the membrane 40. The centering means may also consist of a series of centering cables 66 (see FIG 11) which attach to a
5 spring 90 or tether 85 from the centering rim 65 or the membrane 40, to assure that centering occurs with placement.

Optionally electronics, such as sensors 300 and chips 310, built into the membrane may be used to
10 provide data about hemodynamics pressure, flow rates, temperature, heart rates, and electrical signals in the heart. When the membrane is placed in the left atrial appendage 13 the sensors 300 may measure pressures in the atria or atrial appendage. The sensors may also
15 measure ventricular end diastolic pressures through the open mitral or cuspid valves. Other information about the heart may be gathered such as noise from accelerometers to detect leakage, valve efficiency, activity levels of the patient and other noise related
20 data. The sensors 300 may also be blood oxygen sensors. The chip 310 may use telemetry to transmit the information gathered by the sensors 300 and processed or stored by the chip 310 to receiving devices to aid in the treatment of the patient.

25 In FIG. 6 the protective bulbs 55 are removed from the flexible prongs 50 of FIG. 5 such that flexible prongs 50 puncture the walls of the left atrial appendage 13 and secure the membrane 40 in place. The flexible prongs 50 may penetrate into the
30 atrial appendage wall or extend through the atrial appendage wall. The prongs may have barbed ends 51 to prevent the prongs from withdrawing from the atrial appendage wall.

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The membrane 40 has centering rim 65 attached for centering the membrane in the ostium 20 and marker 320 in the membrane 40 for observing the position of the membrane while it is being inserted. The marker
5 may be used for x-ray or ultrasound observation.

Although Nitinol[®] was cited above as a type of shape memory alloy prong material which can be used, any type memory alloy may be used. Such alloys tend to have a temperature induced phase change which will
10 cause the material to have a preferred configuration when heated above a certain transition temperature. Other metals which may be used as prongs include corrosion resistant spring metals such as Elgiloy[®] or spring tempered steel.

15 Another embodiment of the invention is shown in FIG. 7. It is similar to the embodiment shown in FIG. 5. The embodiment in FIG. 7 has a stent 60 attached to the membrane 40 for expanding in the ostium 20 helping to secure the membrane 40 thereto. The
20 prongs 50 operate in the same manner as in FIG. 5 hugging the inner walls of the left atrial membrane 13 to secure the membrane 40 to cover the ostium 20. The stent 60 may also be made from Nitinol[®], Elgiloy[®] or another expandable spring loaded or balloon expandable
25 material.

The membrane 40 may be self centering over the ostium 20 of the left 13 atrial appendage, by placing the stent 50 into the ostium wherein the stent plugs the ostium with the membrane 40 centered in the
30 stent. Further the prongs 50 fit against the wall of the left atrial appendage 13 of or within the lumen of the ostium 20 to center the membrane 40 over the ostium 20.

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In FIG. 8 the protective bulbs 55 are removed from the flexible prongs 50 of FIG. 7 such that flexible prongs 50 puncture the walls of the left atrial appendage 13 and secure the membrane 40 in place. The flexible prongs 50 may penetrate into the atrial appendage wall or extend through the atrial appendage wall. The prongs may have barbed ends 51 to prevent the prongs from withdrawing from the atrial appendage wall.

10 In the embodiment shown in FIG. 9 a larger expandable stent 70 is used to both engage the sides of the ostium 20 and hug the inside walls of the left atrial membrane 13. Again the stent may be made of Nitinol®, Elgiloy® or other material which may be delivered in a catheter and expanded to the proper size and shape to securely hold the membrane 40 over the ostium 20 to prevent blood from entering the left atrial appendage 13 and for preventing thrombosis 30 from exiting.

20 FIG. 10 shows another embodiment of the invention wherein the membrane 40 is secured over the ostium 20 by means of an anchor 80 which is driven into or through the wall of the left atrial appendage 13 and secured therein by the surface area of the anchor so that it will not pull out of or through the wall of the left atrial appendage 13 or cause embolism from the left atrial appendage 13. A tether 85 is attached to the anchor 80 and to the membrane 40 to secure the membrane 40 snugly against the ostium 20. A substance 270 such as thrombin, activated fibrinogen, or other biologic filler may be placed in the left atrial appendage 13 by injection through a catheter after the membrane 40 is in place such that blood is clotted in

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the atrial appendage so that it can not escape. The device delivery catheter itself may have a port for this injection. The port may also be used to inject contrast such as echocardiographic contrast that can be immediately visualized, and examined to determine whether there is a good seal between the ostium of the appendage and the device. The substance 270 injected into the atrial appendage may also be a sealant or filler to seal the membrane against leakage from the atrial appendage. The sealant material, filler material or blood clotting material may be used with any of the embodiments of the invention.

In another embodiment the catheter may inject a chemical ablation agent such as ethanol to ablate the myocardial cells in the sealed off atrial appendage and thus limit atrial fibrillation by limiting or eliminating electrical propagation in the atrial appendage.

FIG. 11 shows another embodiment of the invention wherein membrane 40 has a spiral spring 90 in addition to the anchor 80. The spiral spring 90 can be used in conjunction with or separately from the tether 85 to pull the membrane 40 against the ostium 20. Although a spiral spring 90 has been shown in FIG. 9 the shape used may be oval, cylindrical, oblong, or other shape to connect the anchor 80 to the membrane 40. In another embodiment shown in FIG. 12 the spiral spring 90 may fill the volume of the left atrial appendage 13 securing the membrane 40 to the ostium 20. The spiral spring 90 filling the left atrial appendage 13 may also have an anchor 80 and tether 85 to help secure the membrane 40 to the ostium 20. Alternatively centering rim 65 may be used as shown in

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FIG. 11 to center the membrane 40 over ostium 20 of left atrial appendage 13. Centering cables 66 connected to spring 90 and either membrane 40 or centering rim 65 may also be used to center the
5 membrane 40 over the ostium 20.

FIG. 13 shows yet another means of securing the membrane 40 over the ostium 20. In this embodiment membrane 40 is directly attached to the ostium 20 by an adhesive 100.

10 FIG. 14 shows a delivery catheter 125 containing a collapsed porous membrane 40 and a collapsed disk 130 connected to the porous membrane 40 by a spring 90 on catheter 21. The disk 130 may be made of a flexible woven metal or a flexible woven
15 metal with a thin porous polymer sandwiched inside. Disk 130 may also be a polymer weave. The disk 130 is flexible and compresses or folds so it fits into the delivery catheter 125 and expands to its desired shape after release from the delivery catheter 125.
20 Similarly membrane 40 compresses or folds to fit into the delivery catheter 125 and expands to its desired shape after release. FIG. 15 shows the porous membrane 40, disk 130 and spring 90 from FIG. 14 in an expanded configuration outside of the delivery catheter 125.

25 FIG. 15 shows the spring 90 connecting the porous membrane 40 and the disk 130 for urging them together. In other embodiments an elastic tether or a tether with teeth and a pawl on the porous membrane 40 to form a ratchet can also be used to pull the porous
30 membrane 40 and the disk 130 together.

FIG. 16 shows the device of FIGS. 15 applied to the left atrial appendage 13 having thrombus 30. After the device is applied the spring 90, pulls the

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disk 130 toward the porous membrane 40 collapsing the left atrial appendage 13 and trapping the thrombus 30 therein as shown in FIG. 17.

FIG. 18 shows an alternate embodiment of the device in FIGS. 16 and 17 wherein the catheter 21 is equipped with a vacuum 140 for sucking out blood and thrombosis 30 found in the left atrial appendage 13. The vacuum 140 will help collapse the left atrial appendage 13 such that spring 90 need not be as large as in FIG. 16.

FIG. 19 shows an alternative embodiment of the device where the membrane 150 is inserted into the left atrial appendage 13 and fills it securing the membrane 150 therein. The membrane 150 may be delivered in a catheter as a compressed material and expanded in the atrial appendage 13 or be delivered in a liquid form which will fill the atrial appendage and be transformed into a membrane by curing with another chemical delivered by the catheter or with the aid of a UV light supplied through a fiber optic cable in the catheter 21. By filling the left atrial appendage 13 with a membrane material 150 no blood can enter to pool and become a thrombus 30 and no thrombus 30 can exit to cause heart attacks, strokes and ischemia.

FIGS. 20-22 show another embodiment of the invention using an umbrella principle for securing the membrane 40 against the ostium 20. FIG. 17 shows closed umbrella struts 160 entering the ostium 20 of left atrial appendage 13. The membrane 40 is some distance back from the umbrella struts 160 at the bottom of the range of teeth 195 on pole 170. FIG. 21 shows the umbrella struts inside of the left atrial appendage 13 with the struts 160 open. Umbrella

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opening structure 175 on pole 170 pushes the struts out to the umbrella open position. The umbrella opening structure 175 can be pushed to the open position or have a spring loaded mechanism to push the struts 160 to the open position. The ends of the umbrella struts 160 engage the left atrial appendage wall around the ostium 20 and prevent the umbrella from being withdrawn from the left atrial appendage 13. The ends of the umbrella struts 160 that engage the atrial appendage wall may be blunted or have bulbs on the tips or have padding so as not to puncture the left atrial appendage 13. FIG. 22 shows the membrane 40 drawn up against the ostium 20 by ratcheting the membrane along pole 170. The pawl mechanism 200 engages teeth 195 on pole 170 and is moved forward to snugly block the ostium 20 with the membrane 40.

FIG. 23 shows a stent 260 applied to the ostium 20 of left atrial appendage 13. The stent 260 expands after leaving a delivery catheter such that the wall of the stent secures the stent by pressure to the ostium 20. Membrane 240 folds or is compressed into the delivery catheter and expands as the stent 260 expands and lodges in the ostium 20 of the left atrial appendage 13.

FIG. 24 shows the left atrial appendage 13 compressed such that the volume of the atrial appendage is reduced to almost nothing. With the volume reduced the atrial appendage will not have a large volume of blood which can produce a thrombus. In the embodiment shown disk 130 and spring 90 pull the left atrial appendage 13 toward membrane 40. Although FIG. 24 shows the use of a disk 130 and spring 90 to act on the left appendage any method to reduce the volume of the

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atrial appendage as much as possible may be used. In addition to physically reducing the volume a substance 270 may be injected into the appendage to further limit its volume, or to clot the blood already present
5 therein.

As shown in FIG. 24 the membrane 40 is much larger than the ostium 20. The over size membrane 40 may be used in all embodiments to ensure that the ostium 20 is completely blocked.

10 The devices described above may be percutaneously delivered to the left and right atrial appendages 13, 23 respectively. The devices may have materials in them which enhance visualization or imaging by ultrasound, x-ray or other means making it
15 easier for the device to be implanted and accurately centered over the ostium 20 of the atrial appendage 13. This may consist of small beads placed strategically on the membrane, the connecting elements, or on the anchors. Referring to FIG. 1 catheter 21 is seen
20 entering the heart by way of the aorta 12 to the left ventricle 16 passing through the mitral valve 17 and then entering the left atrial appendage 13 to apply the porous membrane 40 in one of the embodiments as disclosed above. In FIG. 2 the catheter 21 enters the
25 heart from the femoral vein, passes through the inferior vena cava 18 to the right atrium and then passes through the fossa ovalis 19 or through the septum 29 into the left atrium 11 and then approaches the left atrial appendage 13 to apply the porous
30 membrane 40 thereto. FIG. 3 shows the catheter 21 being applied to the right atrial appendage 23. Catheter 21 may enter the heart through the jugular

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vein 28 or the femoral vein to the inferior vena cava 18.

It should be understood that the invention may be practiced with numerous means of attaching the 5 membrane 40 to cover the ostium 20 of the atrial appendages 13 and 23. Any combination of the attachment means with adhesives, prongs, stents, anchors, disks, tethers or springs may be used. The membrane may also be inside of the atrial appendages 13 10 and 23, or may penetrate the atrial appendage and provide a means to securely lock the membrane device into place. Other means of providing a membrane for blocking blood flow into and blood clots out of the atrial appendages not listed may also be used. A 15 substance may be injected into the appendage to limit its volume, or to clot the blood already present.

In all of the above embodiments the blood of the appendage may be facilitated to clot in order to form a large, immobile mass. Alternatively, the 20 appendage may be filled with any substance that will occupy volume. Examples are fibrin, prosthetic polymers (PLLA), Silicone, or a balloon that is delivered and remains in place for long periods of time.

25 All of the above embodiments shown and discussed for the left atrial appendage 13 are also useable on the right atrial appendage 23. Further the invention may be used to close fistulae or connections elsewhere in the body such as the colon or 30 bronchopulmonary systems. The invention may also be used to seal false aneurysms. When the membrane is placed in a false aneurysm it will strengthen the defect and may help to avoid surgery.

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Obviously, many modifications and variations of the present invention are possible in light of the above teachings. It is therefore to be understood that, within the scope of the appended claims, the
5 invention may be practiced otherwise than as specifically described.

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What Is Claimed Is:

1. A method of preventing atrial appendage thrombus from entering the blood stream comprising:

blocking an atrial appendage ostium with a membrane preventing blood from entering the atrial appendage and forming thrombus therein and preventing thrombosis formed therein from leaving.

2. A method of preventing atrial appendage thrombus from entering the blood stream as in claim 1 further comprising:

securing the membrane over the ostium of the atrial appendage by extending prongs from the membrane into the atrial appendage through the ostium.

3. A method of preventing atrial appendage thrombus from entering the blood stream as in claim 2 further comprising:

piercing the wall of the atrial appendage with the prongs extending into the atrial appendage wall to secure the membrane in place.

4. A method of preventing atrial appendage thrombus from entering the blood stream as in claim 2 further comprising:

attaching bulbs on the ends of the prongs to prevent puncturing the interior of the atrial appendages from causing emboli.

5. A method of preventing atrial appendage thrombus from entering the blood stream as in claim 2 further comprising:

- 25 -

centering the membrane over the ostium by prongs attached to the membrane in a circle such that the prongs will position the membrane over the ostium without leaving gaps between the ostium and the membrane.

6. A method of preventing atrial appendage thrombus from entering the blood stream as in claim 2 further comprising:

extending a stent between the membrane and the prongs to engage the ostium of the atrial appendage for securing the membrane to the ostium.

7. A method of preventing atrial appendage thrombus from entering the blood stream as in claim 6 further comprising:

piercing the wall of the atrial appendage with the prongs extending into the atrial appendage wall to secure the membrane in place.

8. A method of preventing atrial appendage thrombus from entering the blood stream as in claim 1 further comprising:

securing the membrane over the ostium of the atrial appendage by extending stent legs into the atrial appendage through the ostium of the atrial appendage to hold the membrane snugly against the ostium of the atrial appendage.

9. A method of preventing atrial appendage thrombus from entering the blood stream as in claim 1 further comprising:

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securing the membrane over the ostium of the atrial appendage by extending an anchor into or through the wall of the atrial appendage and attaching a tether between the atrial appendage and the membrane for holding the membrane snugly against the ostium of the atrial appendage.

10. A method of preventing atrial appendage thrombus from entering the blood stream as in claim 9 further comprising:

providing an elastic tether for sealing the membrane over the ostium of the atrial appendage.

11. A method of preventing atrial appendage thrombus from entering the blood stream as in claim 1 further comprising:

securing the membrane over the ostium of the atrial appendage by inserting an anchor in the wall of the atrial appendage and attaching a spring between the anchor and the atrial appendage to urge the membrane against the ostium of the atrial appendage.

12. A method of preventing atrial appendage thrombus from entering the blood stream as in claim 1 further comprising:

providing a spiral spring connected to the membrane, for a snug filling of the atrial appendage, and sealing the membrane over the ostium of the atrial appendage.

13. A method of preventing atrial appendage thrombus from entering the blood stream as in claim 1 further comprising:

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securing the membrane over the ostium of the atrial appendage adhesively.

14. A method of preventing atrial appendage thrombus from entering the blood stream as in claim 1 further comprising:

securing the membrane over the ostium of the atrial appendage by extending a disk through the wall of the atrial appendage and attaching a tether between the atrial appendage and the membrane for holding the membrane snugly against the ostium of the atrial appendage.

15. A method of preventing atrial appendage thrombus from entering the blood stream as in claim 14 further comprising:

employing an elastic tether for urging the membrane snugly against the ostium of the atrial appendage.

16. A method of preventing atrial appendage thrombus from entering the blood stream as in claim 1 further comprising:

attaching the membrane to the ostium of the atrial appendage by extending a disk through the wall of the atrial appendage and attaching a spring between the atrial appendage and the membrane for urging the membrane snugly against the ostium of the atrial appendage.

17. A method of preventing atrial appendage thrombus from entering the blood stream as in claim 1 further comprising:

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vacuuming the atrial appendage for removing thrombus from therein and for collapsing the atrial membrane.

18. A method of preventing atrial appendage thrombus from entering the blood stream as in claim 1 further comprising:

blocking the atrial appendage ostium by filling the atrial appendage with a membrane material.

19. A method of preventing atrial appendage thrombus from entering the blood stream as in claim 1 further comprising:

securing the membrane over the ostium of the atrial appendage by extending a plurality of umbrella struts on an umbrella pole into the atrial appendage while the umbrella struts are in a closed position and opening the umbrella struts in the atrial appendage such that the umbrella struts engage the atrium appendage wall and can not be withdrawn through the ostium then moving the membrane on the umbrella pole to secure it in position on the opposing side of the ostium holding the ostium wall between the membrane and the umbrella struts thus securing the membrane over the ostium of the atrial appendage.

20. A method of preventing atrial appendage thrombus from entering the blood stream as in claim 1 further comprising:

attaching the membrane to the ostium of the atrial appendage by extending a collapsible stent into the ostium such that the stent expands and engages the circumference of the ostium and attaching a

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collapsible membrane across the lumen of the stent such that opening the stent stretches the membrane across the lumen of the stent thus blocking the ostium.

21. A method of preventing atrial appendage thrombus from entering the blood stream as in claim 1 further comprising:

coating the membrane with an anticoagulant drug to prevent thrombosis.

22. A method of preventing atrial appendage thrombus from entering the blood stream as in claim 1 further comprising:

providing a porous membrane for encouraging endothelial cells to grow in the membrane thus providing a cell wall over the membrane to prevent thrombosis.

23. A method of preventing atrial appendage thrombus from entering the blood stream as in claim 1 further comprising:

injecting a sealant material into the atrial appendage to seal the membrane against the ostium to prevent leakage.

24. A method of preventing atrial appendage thrombus from entering the blood stream as in claim 1 further comprising:

injecting a filler material into the atrial appendage to reduce the volume of the atrial appendage.

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25. A method of preventing atrial appendage thrombus from entering the blood stream as in claim 1 further comprising:

injecting a blood coagulating substance into the atrial appendage to clot the blood therein and prevent it from flowing out of the atrial appendage.

26. A method of preventing atrial appendage thrombus from entering the blood stream as in claim 1 further comprising:

injecting an ablative chemical into the atrial appendage to ablate myocardial tissue thus preventing electrical propagation of atrial fibrillation.

27. A method for preventing atrial appendage thrombus from entering the blood stream as in claim 1 further comprising:

providing a means for centering the membrane over the ostium of the atrial appendage to provide a good seal.

28. A method for preventing atrial appendage thrombus from entering the blood stream as in claim 27 wherein the means for centering the membrane over the ostium comprises:

attaching a centering rim to the membrane for insertion into the ostium of the atrial appendage.

29. A method for preventing atrial appendage thrombus from entering the blood stream as in claim 27

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wherein the means for centering the membrane over the ostium comprises:

- attaching a centering rim to the membrane for insertion into the ostium of the atrial appendage,

- attaching a securing means to the wall of the atrial appendage and connecting the securing means a spring between the securing means and the membrane to urge the membrane against the ostium of the atrial appendage,

- attaching a plurality of cables from the spring to the membrane to center the membrane over the ostium of the atrial appendage.

30. A method for preventing atrial appendage thrombus from entering the blood stream as in claim 27 wherein the means for centering the membrane over the ostium comprises:

- attaching a centering rim to the membrane for insertion into the ostium of the atrial appendage,

- attaching a securing means to the wall of the atrial appendage and connecting the securing means a spring between the securing means and the membrane to urge the membrane against the ostium of the atrial appendage,

- attaching a plurality of cables from the spring to the centering rim of the membrane to center the membrane over the ostium of the atrial appendage.

31. A method for preventing atrial appendage thrombus from entering the blood stream as in claim 27

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wherein the means for centering the membrane over the ostium comprises:

attaching a securing means to the wall of the atrial appendage and connecting the securing means a spring between the securing means and the membrane to urge the membrane against the ostium of the atrial appendage,

attaching a plurality of cables from the spring to the membrane to center the membrane over the ostium of the atrial appendage.

32. A method for preventing atrial appendage thrombus from entering the blood stream as in claim 27 wherein the means for centering the membrane over the ostium comprises:

attaching a centering rim to the membrane for insertion into the ostium of the atrial appendage,

attaching a securing means to the wall of the atrial appendage and connecting the securing means a tether between the securing means and the membrane to urge the membrane against the ostium of the atrial appendage,

attaching a plurality of cables from the tether to the centering rim of the membrane to center the membrane over the ostium of the atrial appendage.

33. A method for preventing atrial appendage thrombus from entering the blood stream as in claim 27 wherein the means for centering the membrane over the ostium comprises:

attaching a securing means to the wall of the atrial appendage and connecting the securing

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means a tether between the securing means and the membrane to urge the membrane against the ostium of the atrial appendage,

attaching a plurality of cables from the tether to the membrane to center the membrane over the ostium of the atrial appendage.

34. A method for preventing atrial appendage thrombus from entering the blood stream as in claim 27 wherein the means for centering the membrane over the ostium comprises:

attaching a centering rim to the membrane for insertion into the ostium of the atrial appendage,

attaching a securing means to the wall of the atrial appendage and connecting the securing means a tether between the securing means and the membrane to urge the membrane against the ostium of the atrial appendage,

attaching a plurality of cables from the tether to the membrane to center the membrane over the ostium of the atrial appendage.

35. A method for preventing atrial appendage thrombus from entering the blood stream as in claim 1 further comprising:

attaching markers to the membrane for observing the position of the membrane as it is placed in the ostium of the atrial appendage.

36. A method for preventing atrial appendage thrombus from entering the blood stream as in claim 1 further comprising:

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attaching sensors to the membrane for providing information about the patient..

37. A membrane for blocking an atrial appendage ostium comprising:

a membrane,
a means for blocking the ostium of the atrial appendage with the membrane such that no blood enters the atrial appendage to form a thrombus and no thrombus escapes the atrial appendage.

38. A membrane for blocking the ostium of an atrial appendage ostium as in claim 37 wherein:

the means for blocking the atrial appendage comprises a membrane over the ostium, the membrane having a plurality of prongs extending through the ostium and hugging the walls of the atrial appendage such that the membrane is held firmly over the ostium.

39. A membrane for blocking an atrial appendage ostium as in claim 38 wherein:

memory alloy prongs are used to expand to the desired shape inside of the atrial appendage to firmly hold the membrane over the ostium.

40. A membrane for blocking an atrial appendage ostium as in claim 37 wherein:

a bulb on the tip of each of the prongs prevents embolisms caused by the prongs impaling the atrial appendage walls.

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41. A membrane for blocking an atrial appendage ostium as in claim 37 wherein:
the prongs pierce the atrial appendage wall to secure the membrane in place.

42. A membrane for blocking an atrial appendage ostium as in claim 37 wherein:
the prongs are attached to the membrane in a circle such that the prongs will center the membrane over the ostium.

43. A membrane for blocking an atrial appendage ostium as in claim 37 wherein:
a stent between the membrane and the prongs engages the diameter of the ostium of the atrial appendage and holds the membrane securely in place over the ostium.

44. A membrane for blocking an atrial appendage ostium as in claim 43 wherein:
the prongs pierce the atrial appendage wall to secure the membrane in place.

45. A membrane for blocking an atrial appendage ostium as in claim 37 wherein:
the means for blocking the ostium comprises, a plurality of stent legs attached to the membrane and extending inside of the atrial appendage through the ostium of the atrial appendage.

46. A membrane for blocking an atrial appendage ostium as in claim 45 wherein:

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memory alloy stent legs are used to expand to the desired shape inside of the atrial appendage to firmly hold the membrane over the ostium.

47. A membrane for blocking an atrial appendage ostium as in claim 37 wherein:

the means for blocking the ostium comprises, an anchor into or through the wall of the atrial appendage and a tether connecting the anchor and the membrane to securely hold the membrane over the ostium of the atrial appendage.

48. A membrane for blocking an atrial appendage ostium as in claim 47 wherein:

the tether is elastic for securely drawing the membrane against the ostium of the atrial appendage.

49. A membrane for blocking an atrial appendage ostium as in claim 37 wherein:

the means for blocking the ostium comprises, an anchor into or through the wall of the atrial appendage and a spring connecting the anchor and the membrane to securely hold the membrane over the ostium of the atrial appendage.

50. A membrane for blocking an atrial appendage ostium as in claim 37 wherein:

the means for blocking the ostium comprises a spiral spring filling the atrial appendage and connected the membrane to securely hold the membrane over the ostium of the atrial appendage.

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51. A membrane for blocking an atrial appendage ostium as in claim 37 wherein:

the means for blocking the ostium comprises an adhesive on the membrane for securing the membrane over the ostium of the atrial membrane.

52. A membrane for blocking an atrial appendage ostium as in claim 37 wherein:

a vacuum removes thrombus from the atrial appendage and reduces the volume of the atrial appendage by suction.

53. A membrane for blocking an atrial appendage ostium as in claim 37 wherein:

the means for blocking the ostium comprises, a disk on the opposite side of the wall of the atrial appendage and a spring connecting the disk and the membrane to securely hold the membrane over the ostium of the atrial appendage.

54. A membrane for blocking an atrial appendage ostium as in claim 37 wherein:

the means for blocking the ostium comprises, a disk on the opposite side of the wall of the atrial appendage and a tether connecting the disk and the membrane to securely hold the membrane over the ostium of the atrial appendage.

55. A membrane for blocking an atrial appendage ostium as in claim 37 wherein:

the means for blocking the ostium comprises a membrane material filling the atrial appendage.

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56. A membrane for blocking an atrial appendage ostium as in claim 37 wherein:

the means for blocking the ostium comprises a pole having a plurality of umbrella struts at one end,

an umbrella strut opening mechanism for extending the umbrella struts from a closed position with the umbrella struts adjacent the pole to an open position with the umbrella struts extending radially away from the pole, such that the umbrella struts may be inserted through the ostium of an atrial appendage in the closed position and then opened such that the umbrella struts engage the atrial appendage wall and can not be removed from the ostium,

the pole having a plurality of teeth,
a pawl in the membrane for forming a ratchet in combination with the teeth to move the membrane along a length of the pole into a locked position securing it against the ostium of the atrial appendage opposite the umbrella struts.

57. A membrane for blocking an atrial appendage ostium as in claim 37 wherein:

the means for blocking the ostium a collapsible stent for insertion into the ostium such that the stent expands and engages the circumference of the ostium and attaching a collapsible membrane across the lumen of the stent such that opening the stent stretches the membrane across the lumen of the stent thus blocking the ostium.

58. A membrane for blocking an atrial appendage ostium as in claim 37 wherein:

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an anticoagulant drug on the membrane to prevent thrombosis.

59. A membrane for blocking an atrial appendage ostium as in claim 37 wherein:

an ablative chemical injected into the atrial appendage ablates myocardial tissue thus preventing electrical propagation of atrial fibrillation.

60. A membrane for blocking an atrial appendage ostium as in claim 37 wherein:

the membrane is a porous membrane to encourage endothelial cells to grow in the pores of the membrane thus providing a cell wall over the membrane to prevent thrombosis.

61. A membrane for blocking an atrial appendage ostium as in claim 37 wherein:

the membrane is a metal mesh to encourage endothelial cells to grow in the pores of the membrane thus providing a cell wall over the membrane to prevent thrombosis.

62. A membrane for blocking an atrial appendage ostium as in claim 37 wherein:

a substance in the atrial appendage seals the membrane against leakage.

63. A membrane for blocking an atrial appendage ostium as in claim 37 wherein:

a substance in the atrial appendage fills the atrial appendage and reducing its volume.

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64. A membrane for blocking an atrial appendage ostium as in claim 37 wherein:

a coagulant in the atrial appendage coagulates the blood therein such that it can not escape the atrial appendage.

65. A membrane for blocking an atrial appendage ostium as in claim 37 wherein:

the membrane has a means for centering the membrane over the ostium of the atrial appendage.

66. A membrane for blocking an atrial appendage ostium as in claim 65 wherein the means for centering the membrane over the ostium comprises:

a centering rim on the membrane for placement in the ostium.

67. A membrane for blocking an atrial appendage ostium as in claim 65 wherein the means for centering the membrane over the ostium comprises:

a means for securing a spring to a wall of the atrial appendage and securing the other end of the spring to the membrane,

a plurality of cables on the spring connected to the membrane for centering the membrane over the ostium.

68. A membrane for blocking an atrial appendage ostium as in claim 65 wherein:

a centering rim on the membrane for placement in the ostium,

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a means of securing a spring to a wall of the atrial appendage and securing the other end of the spring to the membrane,

a plurality of cables on the spring connected to the membrane for centering the membrane over the ostium.

69. A membrane for blocking an atrial appendage ostium as in claim 65 wherein:

a centering rim on the membrane for placement in the ostium,

a means of securing a spring to a wall of the atrial appendage and securing the other end of the spring to the membrane,

a plurality of cables on the spring connected to the centering rim on the membrane for centering the membrane over the ostium.

70. A membrane for blocking an atrial appendage ostium as in claim 65 wherein the means for centering the membrane over the ostium comprises:

a means for securing a tether to a wall of the atrial appendage and securing the other end of the tether to the membrane,

a plurality of cables on the tether connected to the membrane for centering the membrane over the ostium.

71. A membrane for blocking an atrial appendage ostium as in claim 65 wherein:

a centering rim on the membrane for placement in the ostium,

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a means of securing a tether to a wall of the atrial appendage and securing the other end of the tether to the membrane,

a plurality of cables on the tether connected to the membrane for centering the membrane over the ostium.

72. A membrane for blocking an atrial appendage ostium as in claim 65 wherein:

a centering rim on the membrane for placement in the ostium,

a means of securing a tether to a wall of the atrial appendage and securing the other end of the tether to the membrane,

a plurality of cables on the tether connected to the centering rim on the membrane for centering the membrane over the ostium.

73. A membrane for blocking an atrial appendage ostium as in claim 65 wherein the means for centering the membrane over the ostium comprises:

markers attached to the membrane for observing the position of the membrane as it is placed in the ostium of the atrial appendage.

74. A membrane for blocking an atrial appendage ostium as in claim 37 wherein, at least one sensor attached to the membrane for monitoring a patient.

75. A method of obstructing openings in the body of a patient comprising:

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non invasively inserting membranes in the openings by use of catheters to block the opening, securing the membrane in place by the membrane lodging against the opening and providing a means for attaching the membrane to body tissue on the opposite side of the opening.

76. A method of obstructing openings in the body of a patient as in claim 75 further comprising:
securing the membrane over a false aneurysm.

77. A method of obstructing openings in the body of a patient as in claim 75 further comprising:
securing the membrane over a fistulae.

78. A method of obstructing openings in the body of a patient as in claim 75 further comprising:
securing the membrane over an ostium of an atrial appendage.

79. A membrane for obstructing openings in the body of a patient comprising:
a membrane,
a means for securing the membrane over the opening by placing the membrane one side of the opening and a means for securing a connecting element to body tissue the opposite side of the opening from the membrane.

80. A membrane for obstructing openings in the body of a patient as in claim 79 wherein:

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a false aneurysm is covered by the
membrane.

81. A membrane for obstructing openings in
the body of a patient as in claim 79 wherein:
a fistulae is covered by the membrane.

82. A membrane for obstructing openings in
the body of a patient as in claim 79 wherein:
an ostium of an atrial appendage is
covered by the membrane.

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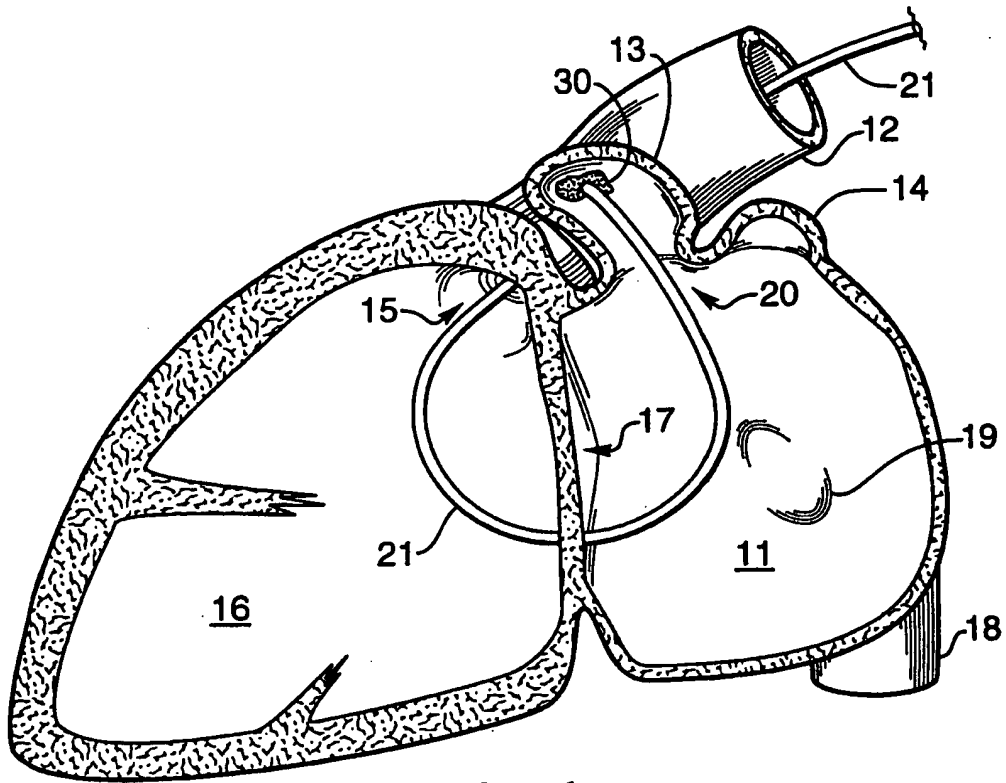


Fig. 1

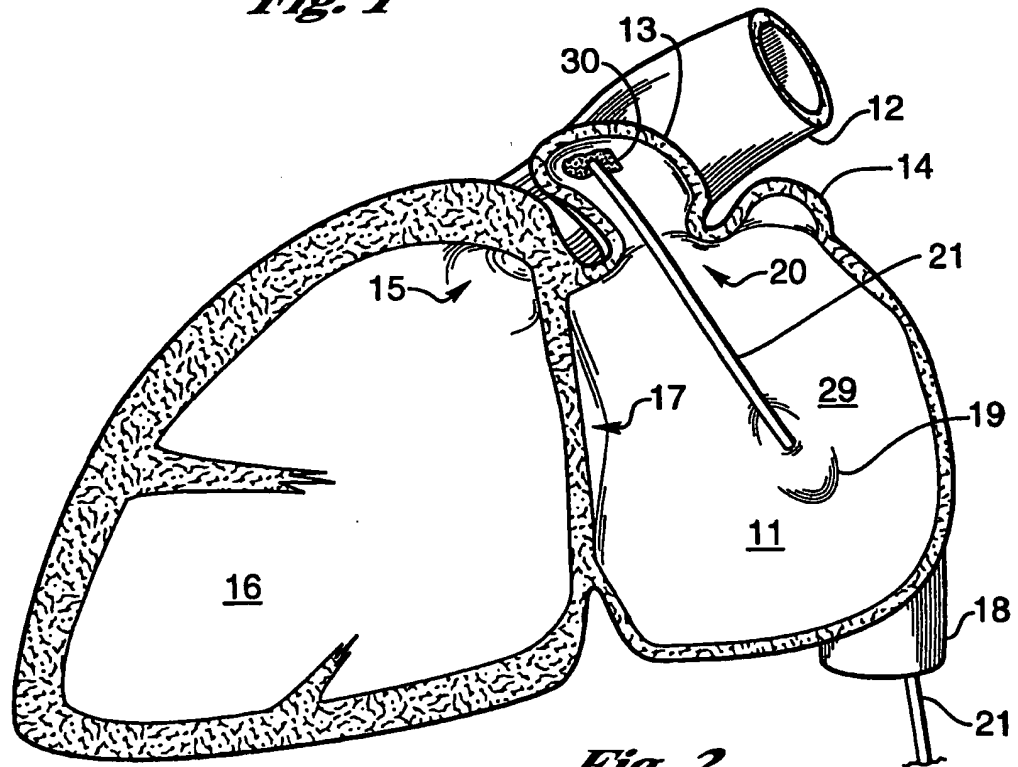


Fig. 2

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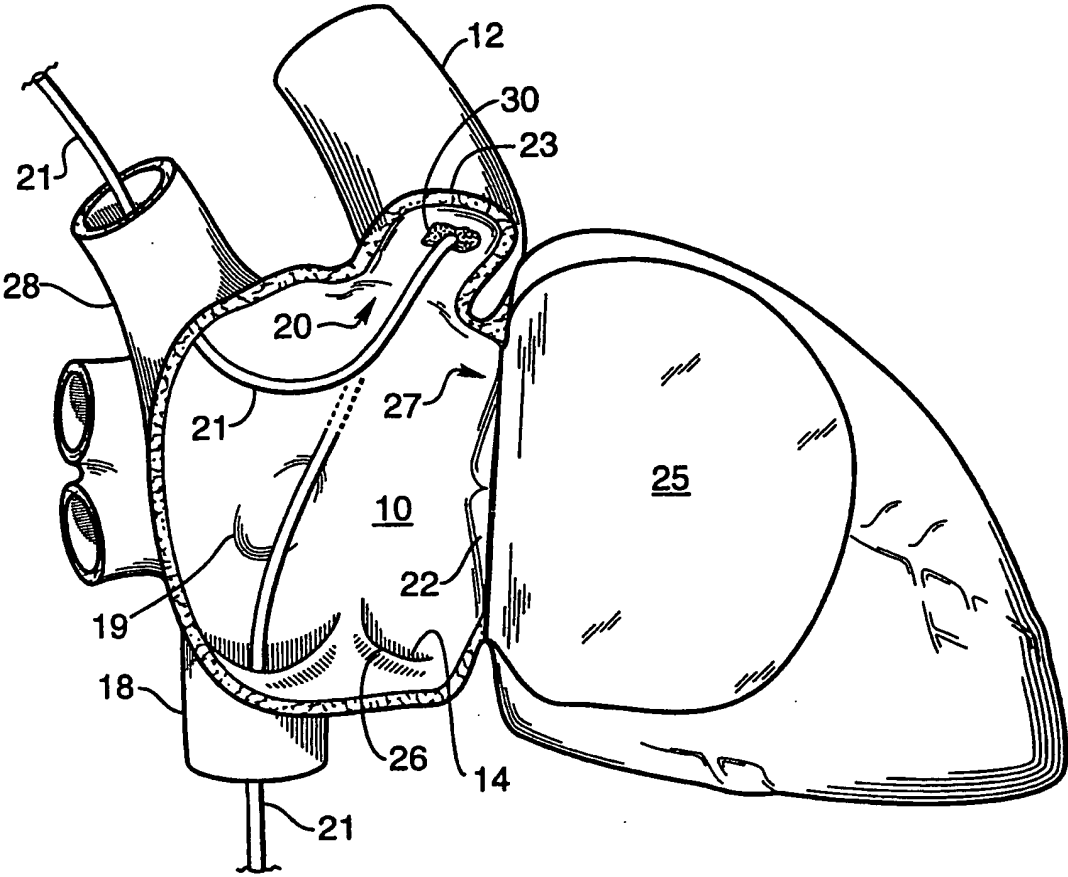


Fig. 3

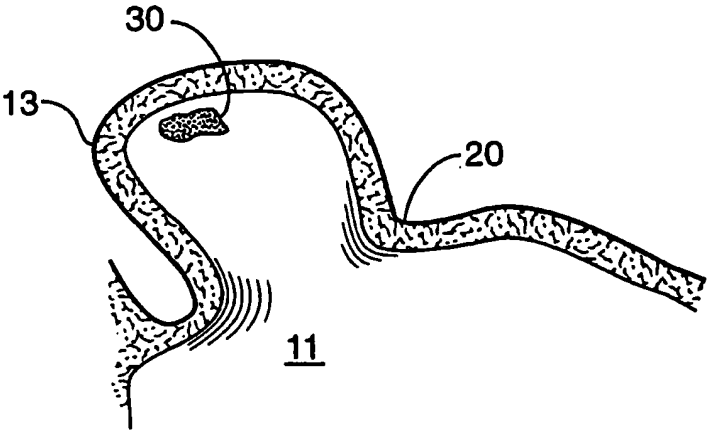
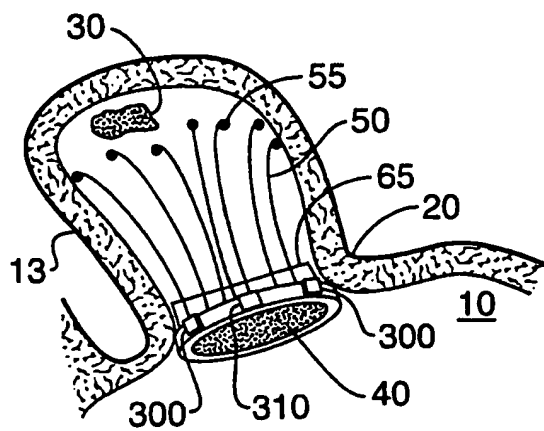
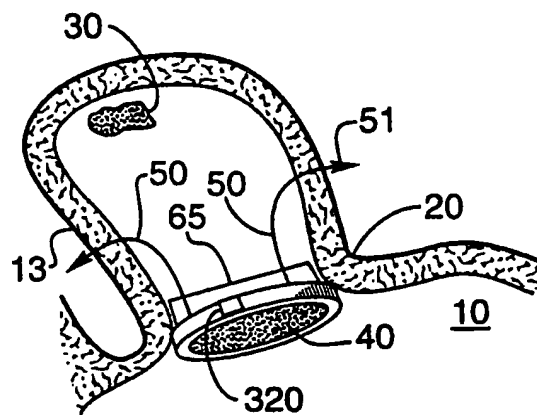
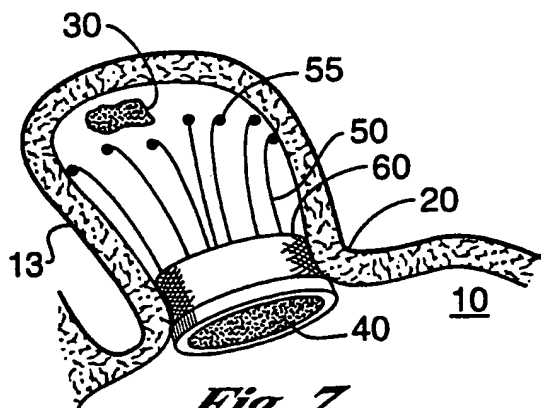
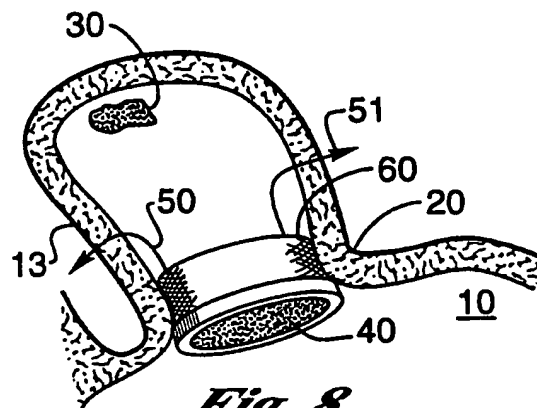
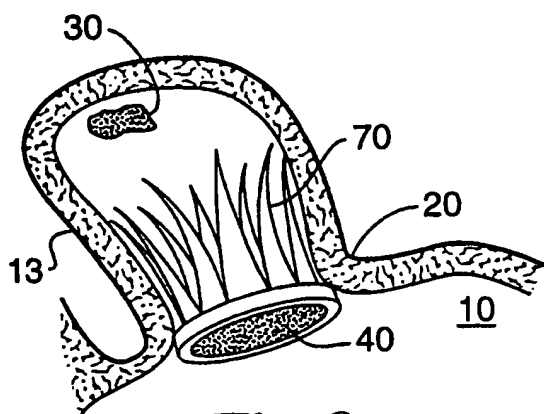
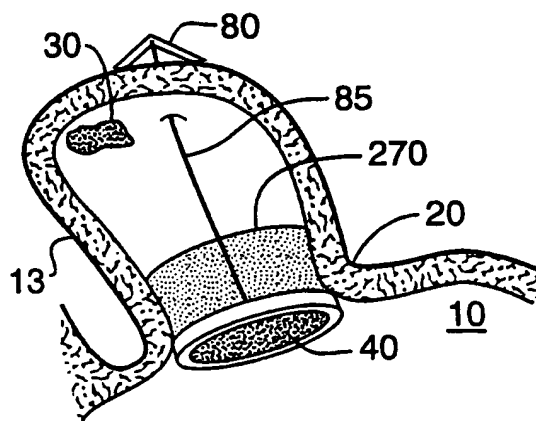


Fig. 4

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*Fig. 5**Fig. 6**Fig. 7**Fig. 8**Fig. 9**Fig. 10*

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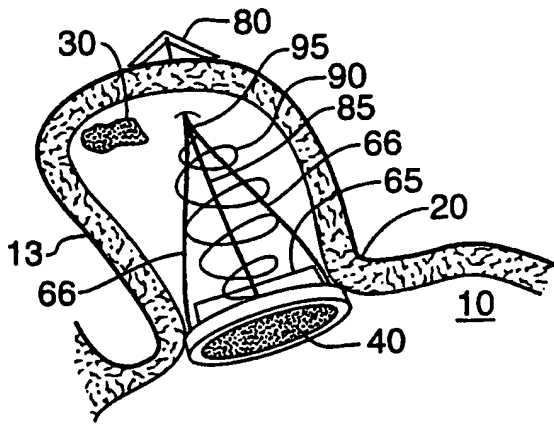


Fig. 11

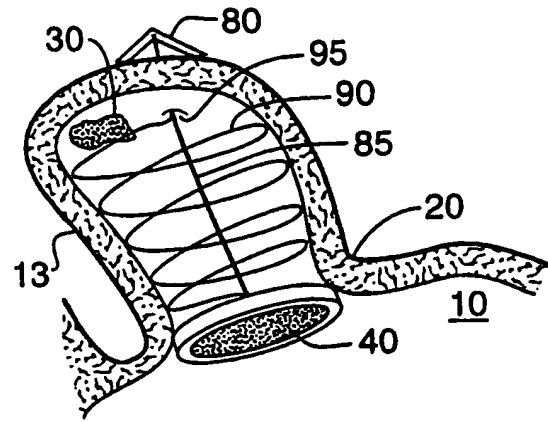


Fig. 12

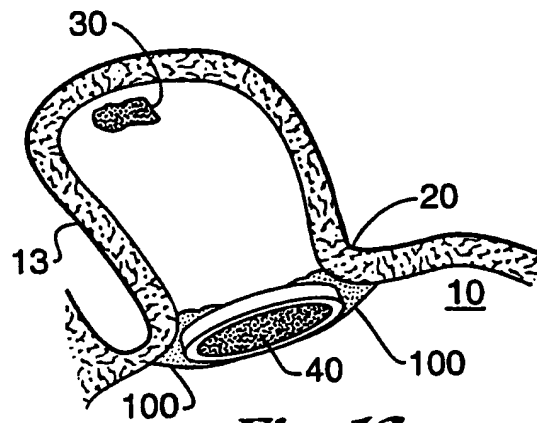


Fig. 13

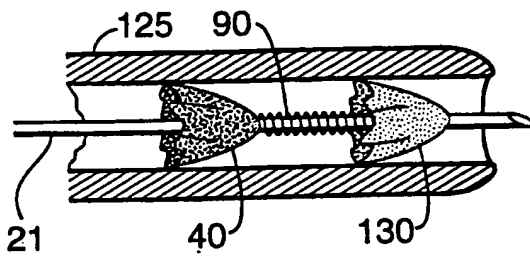


Fig. 14

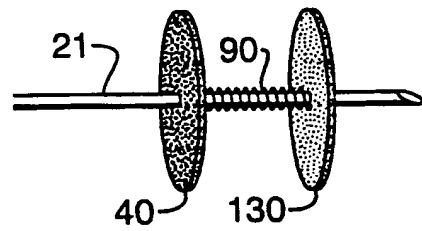
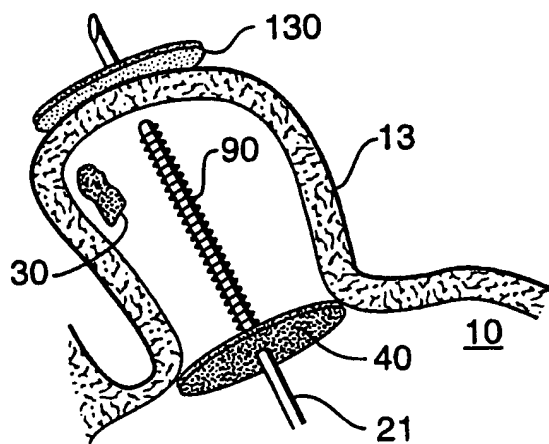
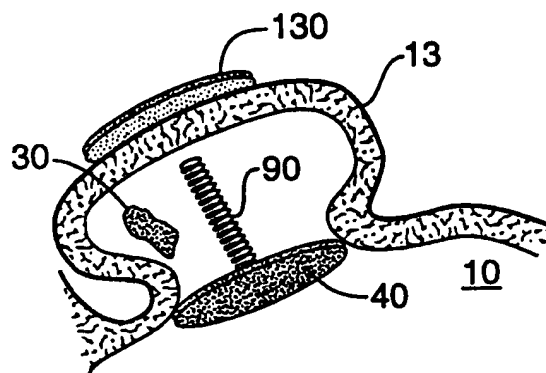
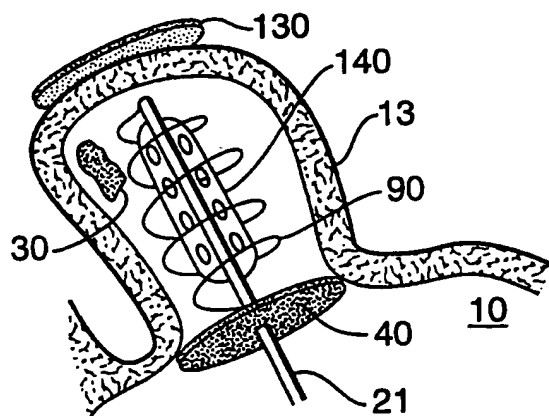
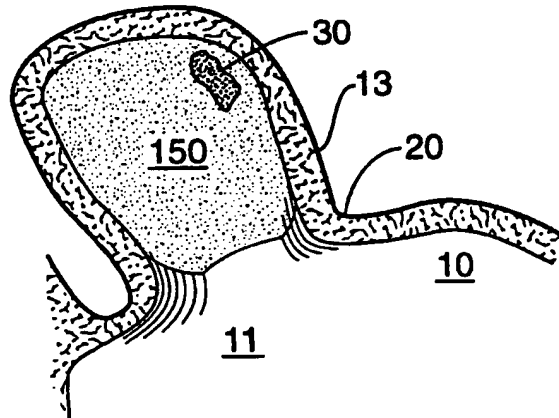


Fig. 15

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*Fig. 16**Fig. 17**Fig. 18**Fig. 19*

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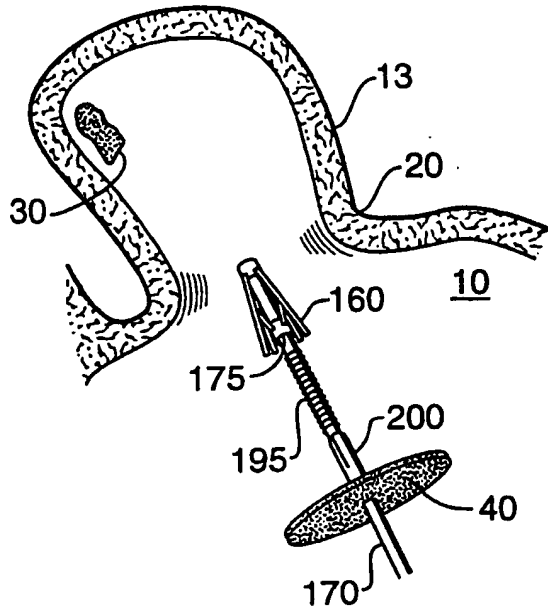


Fig. 20

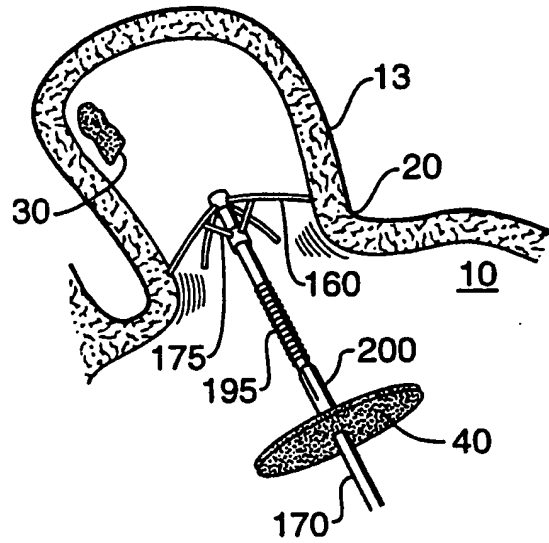


Fig. 21

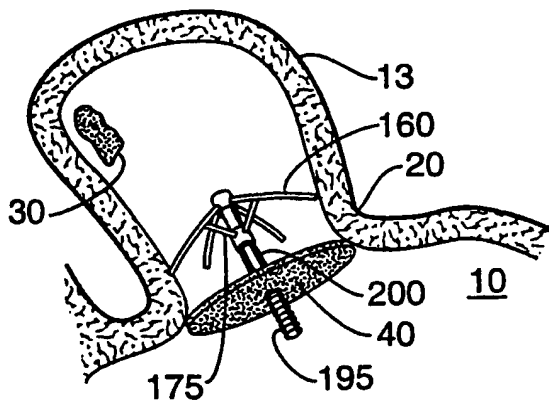


Fig. 22

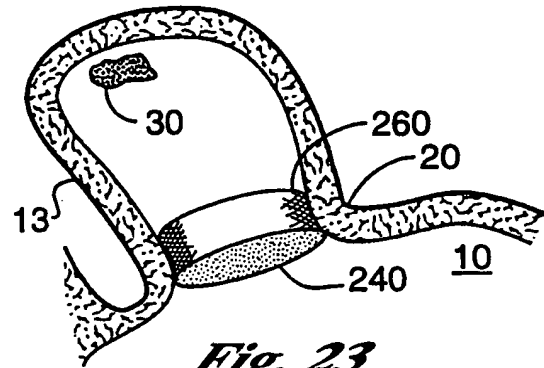


Fig. 23

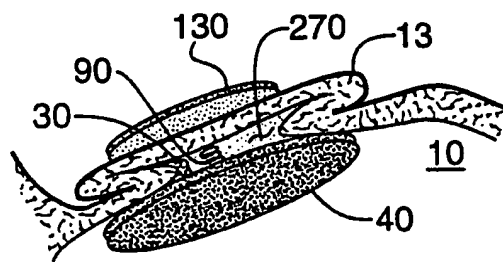


Fig. 24

Int. l. Application No.
PCT/US 00/41415

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